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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,589	05/01/2001	Omolayo O. Famodu	BB1191 DIV	5132

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[REDACTED] EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	(6)

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/846,589	FAMODU ET AL.
	Examiner	Art Unit
	Kathleen M Kerr	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 June 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 44-50 and 52-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 48 and 49 is/are allowed.
- 6) Claim(s) 44-47,50 and 52-56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 11, mailed on February 21, 2003), Applicants filed a response and amendment received on June 24, 2003 (Paper No. 14). Said amendment cancelled Claim 51. Thus, Claims 44-50 and 52-56 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/352,990 filed on July 14, 1999 now USPN 6,255,090.

3. As previously noted, the instant application is not granted the benefit of priority for the U.S. Provisional Application No. 60/092,866 filed on July 15, 1998 because the instant application does not comply with the rules set out in 35 U.S.C. § 119 (e): namely, no common inventors are found between the instant application and the provisional application. Applicants comment in their remarks that Layo O. Morakinyo, an inventor on the provisional application, is the same person as Omolayo O. Famodu, an inventor of the instant application. A petition to this effect has been filed, but not decided. Until the petition is decided, this issue will be held in abeyance by the Examiner.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed on June 24, 2003 (Paper No. 15) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Withdrawn - Objections to the Specification

5. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment.
6. Previous objection to the Abstract is objected to for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.

Previous objection to the specification for now containing an inappropriate amendment is withdrawn by virtue of Applicants' amendment returning page 9 to its originally filed text and page 6 to the amended text.

Maintained - Objections to the Specification

7. Previous objection to the specification for appropriate lacking continuity data in the first paragraph is maintained due to the question of claiming priority to the provisional application (see Priority section above). Appropriate amendment may be due to the specification upon decision of the petition noted above (see M.P.E.P. § 201.11).

Withdrawn - Claim Objections

8. Previous objection to Claim 51 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claim 51 under 35 U.S.C. § 112, second paragraph, as being indefinite for being unclear is withdrawn by virtue of Applicants' cancellation of said claim.
10. Previous rejection of Claim 51 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

11. Previous rejection of Claim 51 under 35 U.S.C. § 102(e) as being anticipated by Lalgudi *et al.* is withdrawn by virtue of Applicants' cancellation of said claim.

NEW REJECTIONS

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 44-47, 50, and 52-56 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides that encode SEQ

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ID NO:10, does not reasonably provide enablement for polynucleotides with low sequence identity with respect to the disclosed encoding polynucleotide, SEQ ID NO:9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The amount of experimentation required of one of skill in the art to make the claimed invention to the full extent of its scope is undue.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

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The instant specification teaches various tRNA synthetases (Asp, Cys, Trp, and Tyr) from plants, specifically *Zea mays*, *Oryza sativa*, *Triticum aestivum* and *Glycine max*. The specification teaches three Cys-tRNA synthetases from plants (from *O. sativa*, *G. max*, and *Z. mays*); the instant claims are drawn to polynucleotides related to the Cys tRNA synthetase from *Zea mays* (SEQ ID NOs: 9 and 10). The art includes several examples of Cys tRNA synthetase encoding genes; however their sequence relatedness is very limited as noted below in "Examiner's Comments". Moreover, the relatedness between the plant Cys-tRNA synthetases disclosed in the instant specification is also limited and not discussed as a genus, i.e., what structural components enable these sequences to encode plant Cys-tRNA synthetases as a group? The art fully enables any DNA encoding SEQ ID NO:10 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other Cys tRNA synthetase genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a Cys tRNA synthetase gene, which is structurally related to SEQ ID NO:9, is not equivalent to the ability to make a Cys tRNA synthetase gene as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its Cys tRNA synthetase-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

Summary of Pending Issues

13. The following is a summary of the issues pending in the instant application:
- a) The specification stands objected to for cited continuity data; relying on a petition related to the provisional application.
 - b) Claims 44-47, 50, and 52-56 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Closest Prior Art and Examiner's Comments

14. The following is reiterated from the previous Office action:
- a) "The closest prior art identified by the Examiner is GenBank Accession Number AB009048, *Arabidopsis thaliana* genomic DNA, chromosome 5 (published December 2, 1997). This GenBank Accession Number teaches a 71,736 bp DNA sequence a portion of which having limited (<50%) similarity to a sequence encoding SEQ ID NO:10 (see attached alignment). This art is clearly not within the scope of Claims 44-50 and 52-56."
 - b) "In addition to noting the above closest prior art, the Examiner is noting the following for clarity and completeness of the record. The instant claims are drawn to a polynucleotide that encodes a cysteinyl tRNA synthetase (Cys-tRS) and that is structurally related to SEQ ID NOs:9 (DNA) and/or 10 (amino acid). From *Zea mays* (corn), SEQ ID NO:10 is a 599 amino acid sequence, and SEQ ID NO:9 exactly encodes said sequence with 2085 base pairs. This sequence does *not* start with a methionine (or the less common valine) and does *not* end with a stop codon. The specification describes SEQ ID NO:10 as a cysteinyl-tRNA

synthetase by virtue of limited homology (40-45%) with putative Cys-tRS's from *H. influenzae* and *E. coli* (see Example 4).

Cys-tRS's in the art range in size from 489-750 amino acids in length, thus, SEQ ID NO:10 is within the art-defined range of enzymes. A putative Cys-tRS from *A. thaliana* is only about 40% identical to that of *H. influenzae* and *E. coli*, as similarly described for the *Zea mays* sequence in the instant specification. From these data, the putative assignment of Cys-tRS functionality for SEQ ID NO:10 is reasonable and fulfills the utility requirement.

Other plant Cys-tRS sequences in the instant application have low homology to a sequence encoding SEQ ID NO:10; *Oryza sativa* at 76% and *Glycine max* at 47% (see attached alignments). Such plant sequences would be expected to have a higher homology to the *Zea mays* sequence (see Peeters *et al.*). Moreover, in GenBank Accession Number AY104190, a slightly longer DNA sequence is disclosed by DuPont's maize mapping group that is 2120 base pairs long encompassing SEQ ID NO:9 exactly end-to-end (see attached alignment); in this case, DuPont does **NOT** identify the sequence as a Cys-tRS. It is noted that in AAD07974 just 5' of the SEQ ID NO:9 corresponding base pairs is a "tga" stop codon and just 3' of SEQ ID NO:9 is a "tga" stop codon. Thus, it would seem that SEQ ID NO:9 is not a part of the full-length open reading frame. However, none of the above data taken alone or together are sufficient to form a *prima facie* case to discount the putative functional assignment of SEQ ID NO:10 by Applicants in the instant specification. Thus, the claims have utility and adequate written description."

Conclusion

15. Claims 48 and 49 are allowed. Claims 44-47, 50, and 52-56 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. The instant Office action is **non-final** due to the new grounds of rejection set forth herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
September 10, 2003

